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EXAMINER	
VENCI, DAVID J	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,735	MINDEN, JONATHAN SAMUEL	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 16, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicant's election of Group I, claims 1-9 and 25-29, without traverse in the reply filed on March 16, 2005.

Claims 10-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim.

Currently, claims 1-9 and 25-29 are under examination.

Specification

The disclosure is objected to because of the following informalities:

> Throughout the Specification, the recitation of "half life" of binding or "half life" of release is indefinite because it is not clear how one skilled in the art can make a capture device having a specific "half-life of binding" or a specific "half life of release" when the definitions of "half-life of binding" and the "half life of release" only take into account the parameter of time (i.e. the amount of time required to covalently bind or release half the protein), and do not take into account initial concentration of reactants as well as the forward and reverse rate constants.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Specifically, the specification does not enable one skilled in the art to make a capture device having a specific "half-life of binding" or a specific "half life of release."

Claim 1 recites a biomolecule capture device "having a half-life of binding of desired biomolecules of less than 1 hour; and a half life of release of desired biomolecules of less than 1 hour." The specification defines the term "binding half life" as the amount of time required to covalently bind half the protein in a solution (see Specification at p. 12, lines 5-7). In addition, the specification defines the term "release half life" as the amount of time required to release half of the protein which is covalently bound (see Specification at p. 12, lines 8-10).

The definitions of "binding half life" and "release half life," as recited in the Specification, do not appear to take into account any reaction rate constants or the initial concentration of maleic anhydride biomolecule-binding compound or the initial concentration of biomolecules. For example, the specification does not appear to specify the concentration of "proteins in a solution" in the definition of "binding half life." In addition, the specification does not appear to specify the concentration of "protein which is covalently bound" in the definition of "release half life."

According to Lodish et al., MOLECULAR CELL BIOLOGY, Section 2.3 (2000), the rate of a chemical reaction is affected by the initial concentration of reactants as well as the forward and reverse rate constants (see

Equations 2-3, 2-4). Here, since the definitions of "half-life of binding" and the "half life of release" only take into account the parameter of time (i.e. the amount of time required to covalently bind or release half the protein), and do not take into account initial concentration of reactants as well as the forward and reverse rate constants, it is not clear how one skilled in the art can make a capture device having a specific "half-life of binding" or a specific "half life of release."

In the decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), the factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Here, the state of the prior art does not appear to recognize the concepts of "half-life of binding" or "half life of release" such that a person of ordinary skill would not be apprised of their definitions or the protocol for their determination. In addition, the Specification does not provide direction to a location in the technical literature to educate a person of ordinary skill as to the concepts of "half-life of binding" or "half life of release" and the protocol for their determination. Finally, the Specification does not provide working examples relating to the measurement of "half-life of binding" or "half life of release." Given Applicant's

limited description of "half-life of binding" or "half life of release," the quantity of experimentation needed to make a capture device having a specific "half-life of binding" or a specific "half life of release" is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specific claim rejections under 35 USC 112, second paragraph, set forth infra, may be considered relevant to other claims not explicitly mentioned, as deemed reasonably appropriate.

In claim 1, the recitation of "the maleic anhydride biomolecule-binding compound having a half life of binding of desired biomolecules of less than 1 hour; and a half life of release of desired biomolecules of less than 1 hour" is indefinite because it is not clear how one skilled in the art can make a capture device having a specific "half-life of binding" or a specific "half life of release" when the definitions of "half-life of binding" and the "half life of release" only take into account the parameter of time (i.e. the amount of time required to covalently bind or release half the protein), and do not take into account initial concentration of reactants as well as the forward and reverse rate constants.

In claim 1, the recitation of "the maleic anhydride biomolecule-binding compound having a half life of binding of desired biomolecules" is indefinite because it is not clear whether/how "biomolecules" are incorporated into the claimed device. It is not clear whether "biomolecules" is a required claim limitation.

In claims 1 and 25, the recitation of "a maleic anhydride biomolecule-binding compound" is grammatically awkward and is indefinite because it is not clear whether "maleic anhydride biomolecule" and "binding compound" are physically separate entities, or whether "maleic anhydride biomolecule" and "binding compound" are a single entity.

In claims 1 and 25, the hyphen between "biomolecule" and "binding compound" is indefinite because it is not clear whether the hyphen joins a noun (i.e. "biomolecule") with a noun (i.e. "binding compound"), or whether the hyphen joins a noun (i.e. "biomolecule") with an adjective (i.e. "binding"). In addition, the functional relationship represented by "-" is not clear.

In claim 8, the recitation of "the desired biomolecule" lacks antecedent basis in claim 1. It is not clear whether "biomolecules" is a limitation required in claim 1.

In claims 8-9, the recitation of "amine containing compound" is grammatically awkward and is indefinite because it is not clear whether/how "an amine" is capable of containing a compound. In addition, it is not clear whether said "amine containing compound" references "biomolecule", or whether said "amine containing compound" is a physically separate entity from "biomolecule." In claim 9, it is not clear whether "a protein" references said "amine containing compound" and/or said "biomolecule", or whether "a protein" is a physically separate entity from said "amine containing compound" and/or said "biomolecule."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-9, are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al., 203 ARCH. BIOCHEM. BIOPHYS. 774 (1980).

Singh et al. describe a biomolecule capture device comprising a substrate (see Title, "Solid Support") and a maleic anhydride biomolecule-binding compound covalently bound to the surface (see Abstract, "MPE-agarose"). The device of Singh et al. is necessarily capable of "having a half-life of binding of desired biomolecules of less than 1 hour; and a half life of release of desired biomolecules of less than 1 hour", and would be so recognized by persons of ordinary skill in the art.

With respect to claims 2-4, 7, 26 and 28-29, Singh et al. describe a biomolecule capture device comprising aminohexyl agarose (see Abstract, "MPE-agarose") solid support.

With respect to claims 8-9, Singh et al. describe a biomolecule capture device comprising a protein containing an amine (see Abstract, "bovine serum albumin").

Claims 1-3, 5-9, 25 and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (US 6,372,813).

Johnson et al. describe a biomolecule capture device comprising a substrate and a maleic anhydride biomolecule-binding compound covalently bound to the surface (see Fig. 3). The device of Johnson et al. is necessarily capable of "having a half-life of binding of desired biomolecules of less than 1 hour; and a half life of release of desired biomolecules of less than 1 hour", and would be so recognized by persons of ordinary skill in the art.

With respect to claims 2-3 and 28-29, Johnson et al. describe a biomolecule capture device wherein the substrate comprises polyamide (see col. 4, line 59).

With respect to claims 5-6, 25 and 27, Johnson et al. describe a biomolecule capture device comprising dimethyl maleic anhydride (see Fig. 3).

With respect to claims 8-9, Johnson et al. describe a biomolecule capture device comprising a protein containing an amine (see col. 7, lines 45-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5-6 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al., 203 ARCH. BIOCHEM. BIOPHYS. 774 (1980), in view of Kinsella & Shetty (US 4,348,479).

Singh et al. describe a biomolecule capture device as substantially described supra. Singh et al. do not describe a device comprising a dialkyl maleic anhydride.

However, Kinsella & Shetty teach the use of dimethyl maleic anhydride (see col. 3, line 43) for capturing biomolecules (see Title, "proteinaceous material"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the biomolecule capture device of Singh et al. with dialkyl maleic anhydride because Kinsella & Shetty discovered that proteins can be reversibly captured with cyclic anhydrides, including dimethyl maleic anhydride, in as little as 15 minutes (see col. 4, line 26) and released in as little as 20 minutes (see col. 4, line 68).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
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04/14/05